REMARKS

In her communication of March 27, 2001, the Examiner has required restriction between the following three claim groups:

I. Claims 1 and 2, drawn to a pharmaceutical composition comprising tyrosine, an optionally modified allergen, and 3-DMP;

II. Claims 3 and 4, drawn to a method of treating a patient with allergy or preventing allergy comprising administration of the pharmaceutical composition of claim 1; and

III. Claim 5, drawn to a process for the preparation of the pharmaceutical composition of claim 1.

The Examiner bases this restriction requirement on her determination that the three claim groups do not relate to a single general inventive concept on the ground that claim 1 lacks inventive step over:

1. WO 96/34626; and
2. WO 92/16556.

WO 96/34626 is cited as disclosing a pharmaceutical composition comprised of tyrosine and a polymerized allergen. WO 92/16556 is cited as teaching 3-DMPL as a useful adjuvant for the administration of immunogens to a host immune system. The Examiner concludes that it would have been obvious for one of ordinary skill in the art to include 3-DMPL in the composition of WO 96/34626.

Applicants hereby elect with traverse the claims of Group I, claims 1 and 2. The requirement is traversed on the ground that the pending claims are linked by a single inventive concept, and applicants further respectfully submit that the Examiner is incorrect in her determination that the two cited references render the claimed invention obvious. It is a well-established practice that in an international application, a plurality of independent claims in different categories are properly examined together when the independent claims constitute a group of inventions linked by a single general inventive concept. Particularly, in addition to an independent claim drawn to a given product, an independent claim drawn to a process specially adapted for the manufacture of the product and an independent claim drawn to a specific use of

the product constitute a single group acceptable under Rule 13 of the PCT. In the present instance, all claims relate to a pharmaceutical composition comprising tyrosine, an optionally modified allergen, and 3-DMP, and are thus linked by that inventive concept.

The present invention concerns a pharmaceutical composition comprising tyrosine, an optionally modified allergen, and 3-DMPL, as well as methods for use and preparation thereof. The invention is based on the important observation that 3-DMPL can enhance the T cell TH_1 response to an allergen over the TH_2 response. In an allergic subject, the preferential TH_1 response can bring about important clinical benefits. See page 1, lines 8 to 31, of the specification.

WO 96/34626 discloses a pharmaceutical composition comprising tyrosine and a polymerized (optionally modified) allergen. The reference does not disclose or discuss the inclusion of 3-DMPL in the composition.

WO 92/16556 discloses an assertedly novel form of gb160 and a vaccine formulation containing the gp160 and 3-DMPL. On page 8, lines 26 to 29, WO 92/16556 teaches that, in the context of the prophylactic and therapeutic treatment of HIV infections, 3-DMPL is able to stimulate both arms (neutralizing antibody and effector cell-mediated immunity (DTH)) of the immune system. **The application, however, does not teach or suggest that 3-DMPL can be used more widely as a general adjuvant in vaccine formulation**. Furthermore, WO 96/16556 does not teach or suggest that 3-DMPL is suitable for use in allergen formulations and certainly not in formulations comprising tyrosine and optionally polymerized allergens. Moreover, there is nothing in WO 92/16556 that would lead one of skill in the art to believe that 3-DMPL is able to promote the preferential TH_1 activity desired in allergen formulations, but not necessarily desired in vaccine formulations intended to treat and/or offer protection against infectious diseases such as HIV.

Thus, there is nothing in either of the cited references that would motivate one of ordinary skill in the art to include 3-DMPL in the allergen formulation disclosed in WO 96/34626. It is only via the benefit of impermissible hindsight that the Examiner is able to select WO 92/16556, which discloses the use of 3-DMPL in a different composition for a different purpose, and suggest that its teaching be combined with that of WO 96/34626. The Examiner is in error in her

determination that the inventive concept of the application lacks inventive step over the two cited references, and reconsideration of that determination and the examination of all claims is respectfully requested.

In addition, applicants respectfully submit that the claims of all three groups are properly examined together and traverse the restriction requirement on the ground that, as the claims are so closely related, examining the three groups together should be a relatively straightforward matter. That is, there would be no serious burden on the Office should Groups (I), (II), and (III) be kept together. Applicants refer the Examiner to M.P.E.P. §803, wherein it is stated that "[i]f the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits...." This is true even though an application may include claims to distinct inventions.

The Examiner is welcome to contact the undersigned attorney at (650) 851-8501 with any questions concerning this communication.

Respectfully submitted,

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